# PSJ3

# Exhibit 522

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# Hydrocodone Rescheduling Advocacy Group Positions

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Kathy Sapp
US Medical Advocacy, US Medical Affairs

# Organizations Opposed to Reclassification

- The American Academy of Hospice and Palliative Medicine (AAHPM)
- The American Academy of Pain Management (AAPM)
- The American Academy of Pain Medicine (AAPM)
- The American Association of Oral and Maxillofacial Surgeons
- The American Cancer Society Cancer Action Network (ACS CAN)
- The American Dental Association
- The American Optometric Association
- The American Pain Society
- American Society for Pain Management Nursing (ASPMN)
- Center to Advance Palliative Care
- Citizen Advocacy Center (CAC)
- Healthcare Distribution Management Association (HDMA)
- Hematology/Oncology Pharmacy Association
- Hospice and Palliative Nurses Association
- Massachusetts Pain Initiative
- National Association of Chain Drug Stores (NACDS)
- National Community Pharmacists Association (NCPA)
- National Fibromyalgia and Chronic Pain Association
- National Palliative Care Research Center
- Oncology Nursing Society (ONS)
- US Pain Foundation
- Virginia Center
- Wisconsin Pain Initiative

# Sub-Group of Pain Care Forum Participants Who Signed Letter to FDA With Recommendations

## Sub-Group Participants raising concerns to FDA with the advisory Committee's Recommendations:

American Academy of Pain Management (AAPM), American Association of Nurse Assessment Coordination (AANAC), American Cancer Society Cancer Action Network (ACS CAN), American Society of Consultant Pharmacists (ASCP), Amputee Coalition, CarsonCompany, LLC, Citizen Advocacy Center (CAC), Interstitial Cystitis Association, Long Term Care Pharmacy Alliance (LTCPA), Massachusetts Pain Initiative, NADONA, National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), National Fibromyalgia & Chronic Pain Association, National Hospice and Palliative Care Organization, Pain Treatment Topics, US Pain Foundation and the Wisconsin Pain Initiative.

## Key points:

As patient advocacy and health professional organizations, we are committed to combating illegal use of prescription drugs. However, it is also important to consider the unintentional consequences of policy changes that can cause serious difficulties for patients, and even result in harm and further suffering.

"No evidence currently exists to show that reclassifying hydrocodone will curb misuse and abuse of pain medications. In contrast, there is evidence that rescheduling medications to higher classifications can reduce patient access to medications and cause harm" "We stand ready to work with policy makers, the health care community, and drug enforcement officials to develop and promote alternative policies that would address this important public health issue."

# American Academy of Pain Management (AAPM)

## AAPM

**AAPM** is one of the organizations with the Pain Care Forum that signed the letter to the FDA.

Note: Bob Twillman, Ph.D. will be speaking at the public hearing (content of presentation unknown, but last I understood from him was that he had pulled together some numbers that show how costly the reclassification would be for the government)

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# The American Academy of Pain Medicine (AAPM) position

**AAPM**

**AAPM** commented in a press release to the FDA that "it shares the commitment of the petitioners to find ways to curb prescription pain medication harm. In its response, which was signed by 12 members of the Academy's Board of Directors, the response expressed the concern that adoption of the three focal points of the PROP petition to limit the dose, the duration and modify the labeling for opioids that are prescribed for noncancerous pain would have unintended societal consequences."

# American Pain Society (APS) Position

- **APS:**

  "APS does not support their proposed labeling changes, as we perceive an insufficient scientific evidence base to support these recommendations. Further, we are concerned that implementation of these labeling changes which would dictate indications, dosing and duration of opioid treatment will not accomplish the intended goals, but instead have unintended negative consequences for patients including but not limited to untreated pain and loss of access to individualized care." Robert Fillingim, PhD, President, APS

  Letter to FDA signed by APS Board of Directors, Directors at Large, Past Presidents, and Public Policy Committee Members

- Response to Question posed by US MAd to APS 2/4/13 in regard to current position: Per Randi Romanek "Greg Terman (APS) is speaking on behalf of the University of Washington and Ed Michna (APS board member) is speaking on behalf of us and Harvard. We are re-working our position statement so it is not ready to share. I will certainly share the information when the team lets me know it is ready."

# American Academy of Hospice and Palliative Medicine (AAHPM)

- **AAHPM**

  **AAHPM** is "deeply concerned about and opposed to reclassification of hydrocodone-containing combination products as Schedule II substances. AAHPM members are committed to stemming the tide of prescription abuse, misuse and diversion, but believe it is critical to consider the ways in which policy changes with this aim can have negative, unintended collateral effects. Medications containing hydrocodone in combination with other pain relievers are currently prescribed for both acute pain and chronic cancer and non-cancer pain, and we contend reclassification will jeopardize legitimate patient access to what has proven to be highly-effective treatment."

- Answer to question posed by USMAd to AAHPM in regard to upcoming public hearing: Per Randi Romanek "AAHPM will be making brief remarks at the FDA Public Hearing on the **Impact of Approved Drug Labeling on Chronic Opioid Therapy**. AAHPM's President Elect Amy Abernethy, MD FAAHPM, will speak on Feb. 7. We have not finalized her remarks.
- AAHPM will follow up by submitting a letter to the FDA on this matter. The deadline for public comments isn't until April, so we'll be working on the letter. We can share a copy once it's submitted.
- Jackie Kocinski, our Director, Health Policy & Government Relations will be able to pull some talking points for us after the meeting is held."

# Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) Position

- **RSDSA**

  " **RSDSA** is concerned that a change in labeling will adversely affect insurance coverage for medications prescribed for conditions that are no longer listed in the FDA-approved labeling. Such prescribing is called "off- label" use. Off-label prescribing is common and accepted; but denial of coverage for off-label prescriptions is common in the United Kingdom, Europe, and the United States. If that happens, access to opioid pain medication will be limited just as effectively as if the prescriptions were prohibited by the FDA labeling, which they are not. Therefore, RSDSA would like to again make the distinction between labeling of indications for the use of medications by the FDA – which does not limit physicians' prescribing practices – and insurance carriers' denial of coverage for off-label prescriptions – which would limit CRPS patients' access to opioid pain medications covered by health care insurance"

# U.S. Pain Foundation Position

## U.S. Pain Foundation

**U.S. Pain Foundation** " does not feel a "one-size-fits-all" mentality will help the medical or pain community. We agree there is a problem, and are committed to finding ways to remedy it. However, we do not think strict mandates are the answer. "

(Note: Paul Gileno, Founder and President will be at the February 7-8 hearing. He has been training Wendy Foster, working with her to help expand their advocacy efforts. Wendy is scheduled to speak the first day; she is one of the first "Invisible Project" model's who didn't think she could leave her house; now she is one of the U.S. Pain Foundation's top ambassadors.)

# American Chronic Pain Association (ACPA)

- **ACPA**

Penney Cowan with ACPA does not share her position on this topic and cannot attend the hearing because of her position with the FDA